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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,662	12/17/2001	Hideshi Fujiwake	011658	5139

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EXAMINER

DAVIS, DEBORAH A

3

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/015,662

Applicant(s)

FUJIWAKE, HIDESHI

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. Claim 3 is objected to because of the following informalities: Claim 3 recites the limitation "every the constitutive amino acid" in lines 3 and 4, is improper english.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coull et al (USP#5,011,861) in view of Rose et al (Manual of Clinical Laboratory Immunology, Fourth Edition).

Coull et al teaches a method for determining an amino acid or protein sequence and immobilizing them to a solid phase membrane. Coull et al describes that sequences of a protein or peptide can be deciphered by a stepwise chemical or enzymatic degradation from either the amino-(N-) or carboxyl-(C-) terminal end. Single amino acids are removed one by one from the polypeptide chain, separated and identified. This procedure is carried by the Edman degradation method which describes removing one amino acid residue from its amino-terminus with an isothiocyanate (ITC) in a solvent under basic or anhydrous conditions to form various

Art Unit: 1641

side products, such as phenylthiocarbamate (PTC), anilinothiazolinone (ATZ) and phenylthiohydantoins (PTH) derivatives (columns 1 and 2).

Coull et al does not teach the use of a competitive assay to determine the liberated constitutive amino acid.

However, Rose et al teaches the advantages of using a competitive assay that can use either antibodies or antigens on a solid phase. When the assay design used a specific antibody (monoclonal) coated on a solid phase, the antigen in question and the labeled antigen are added simultaneously and compete for binding. As with any competitive assay technique the antigen is incubated with the antibody to form a complex that are removed during wash steps. A labeled antigen is then added to react with any remaining antibody not bound to the first antigen. Competitive assays offer great specificity and are ideal for measuring relatively small molecules that can be obtained in relative purity and in large enough amounts to be labeled. Competitive assays only require small amounts of antibody and are ideal for use in systems that have a limited amount (fixed) of antibody available (Chapter 2, pages 2 and 3).

It would have been obvious to one of ordinary skill in the art to utilize a competitive assay to determine liberated constitutive amino acids as disclosed by Rose et al in the method of Coull et al because competitive assays offer great specificity and are ideal for measuring small molecules that can be obtained in large enough amounts to be labeled.

***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Farnesworth et al teaches a method for compositional tag sequencing of proteins utilizing the conventional Edman degradation method.

B. Kwagh et al teaches a method for sequencing and characterizing polymeric biomolecules using aptamers and a method for producing aptamers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

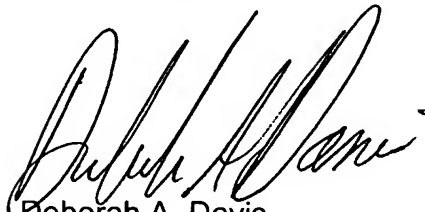
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Application/Control Number: 10/015,662

Page 5

Art Unit: 1641



Deborah A. Davis

CM1, 7D16

March 5, 2003



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03/07/09